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| APPLICATION NO. | FILING DATE | FIRST NAMED INVENTOR | ATTORNEY DOCKET NO. | CONFIRMATION NO. |
|-----------------|-------------|----------------------|---------------------|------------------|
| 09/470,009 | 12/22/1999 | JEONG S. LEE | 003764.P006 | 5656 |

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EXAMINER

LAM, ANN Y

ART UNIT PAPER NUMBER

1641

DATE MAILED: 03/11/2005

Please find below and/or attached an Office communication concerning this application or proceeding.

| | | | |
|------------------------------|--------------------------------------|-----------------------------------|--|
| Office Action Summary | Application No. 09/470,009 | Applicant(s) LEE ET AL. | |
| | Examiner Ann Y. Lam | Art Unit 1641 | |

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE ____ MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 29 November 2004.
- 2a) ☒ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 11-19, 21-23, 25, 26, 51, 53, 56-60, 64 and 65 is/are pending in the application.
- 4a) Of the above claim(s) ____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) ____ is/are allowed.
- 6) ☒ Claim(s) 11-19, 21-23, 25, 26, 51, 53, 56-60, 64 and 65 is/are rejected.
- 7) ☐ Claim(s) ____ is/are objected to.
- 8) ☐ Claim(s) ____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on ____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
 2. ☐ Certified copies of the priority documents have been received in Application No. ____.
 3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- * See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|---|--|
| 1) <input type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413) Paper No(s)/Mail Date. ____ |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | 5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152) |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08) Paper No(s)/Mail Date ____ | 6) <input type="checkbox"/> Other: ____ |

DETAILED ACTION

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

Claims 11-19, 21-23, 25, 26, 51, 53, 56-60, 64-65 are rejected under 35 U.S.C. 103(a) as being unpatentable over Evard, 5,242,396, in view of Lee et al., 6,733,486.

Evard discloses the invention substantially as claimed except for the proximal section of the mandrel being annealed while the distal section of the mandrel is not annealed.

More specifically, as to claim 11, Evard discloses a mandrel (26) having a solid core comprised of a variable stiffness, non-metal material (i.e., plastic, see column 3, lines 38-42, and column 4, lines 28-30) said mandrel uniformly tapered from a proximal section to a distal section (see column 3, lines 38-42, and Figure 1), and said mandrel adapted to reinforce a catheter (see Figure 1.)

As to claim 19, Evard discloses an outer member (17); a hollow inner member (14) extending through said outer member; an outer lumen (18) between said inner and outer members; and a mandrel extending through said outer lumen, said mandrel comprised of a variable stiffness material, said mandrel uniformly tapered, see column

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3, lines 38-42, from a proximal section to a distal section and said mandrel is adapted to reinforce said catheter (see Figure 1.)

As to claims 13, 21 and 56, a diameter of said proximal section is larger than a diameter of said distal section of said uniformly tapered mandrel, i.e., a diameter tapering from the proximal end of the mandrel to the distal end of the mandrel, see Figure 1.

As to claims 14 and 22, the catheter comprises an inflatable member (12, 22 and 23) secured to the catheter shaft, wherein said distal section of said mandrel (26) extends to a location along the length of the catheter located in the inflatable member, see Figure 1.

As to claims 15 and 23, said distal section of said mandrel (26) extends to a location proximal to the inflatable member (see figure 1.)

As to claims 18, 26 and 51 said mandrel (26) is capable of being formed by taper extruding such that said proximal section is stiffer than said distal section (the proximal section is stiffer since the distal section is more tapered.)

As to claims 57, 59, and 65, the mandrel is fixed to the catheter shaft (see column 3, lines 38-39.)

As to claims 58, 60, 64, and 66, an inner tubular member (14) is disposed near the mandrel, wherein the inner tubular member is adapted to receive a guidewire (see column 3, lines 21-26.) Also, as to claim 64, the mandrel is formed of a polymer compatible with a polymer forming the catheter shaft (col. 4, lines 18-30.)

Also, as to claims 12 and 53, Evard does not disclose that the plastic material is PEEK (or polyetheretherketone.)

Lee discloses a mandrel (30) used to reinforce a balloon catheter (10) (col. 4, lines 14-16) is made from pseudo-elastic or shape-memory materials including polymers such as PEEK (col. 4, lines 30-33).

It would have been obvious to one of ordinary skill in the art at the time the invention was made to use PEEK as taught by Lee et al. as the plastic material to form the Evard mandrel since Lee et al. teaches that PEEK provides the advantage of being a pseudo-elastic or shape-memory material suitable for forming a mandrel to reinforce a catheter.

Furthermore, Evard teaches that the proximal end of the polymer mandrel (col. 4, line 30) is flattened and secured within the adapter (13) of the catheter by suitable means, (col. 3, lines 49-53.) Evard gives examples of suitable means such as adhesives but does not list annealing as one of the examples.

Lee et al. teaches that a polymeric mandrel can be secured to a polymeric catheter by conventional means such as adhesives or heat fusion (col. 5, lines 10-12, and col. 4, lines 45-47.) Heat fusion is the same as annealing, which typically involves heating and cooling. (Heat fusion involves heating and subsequently cooling to room temperature, and thus is the same as annealing.) (Also, annealing, or heating, PEEK, according to Applicant's disclosure and arguments, would stiffen the PEEK material, giving it a higher crystallinity than if it was not annealed, or heated.)

Because both Evard and Lee et al. teach use of conventional means to bond a polymeric mandrel to a catheter and both list adhesives as an example of a conventional means, and Lee et al. further lists heat fusion as another example, it would have been obvious to one of ordinary skill in the art at the time the invention was made that heat fusion is a functional equivalent to adhesives for bonding a polymeric mandrel to a catheter.

Response to Arguments

Applicant's arguments with respect to the above rejected claims have been considered but are moot in view of the new ground(s) of rejection.

Conclusion

Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire **THREE MONTHS** from the mailing date of this action. In the event a first reply is filed within **TWO MONTHS** of the mailing date of this final action and the advisory action is not mailed until after the end of the **THREE-MONTH** shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of

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the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Ann Y. Lam whose telephone number is 571-272-0822. The examiner can normally be reached on M-Sat 11-6:00.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Long Le can be reached on 571-272-0823. The fax phone number for the organization where this application or proceeding is assigned is 703-872-9306.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

A.L. 


LONG V. LE
SUPERVISORY PATENT EXAMINER
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03/07/05